201 KAR 2:116. Drug products with therapeutic problems.

RELATES TO: KRS 217.819
STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation lists drug products with active ingredients or dosage forms with potential bioequivalence problems, drugs characteristically possessing a narrow therapeutic index, or categories of agents for which there is either documented evidence of inequivalent therapeutic effect or a potential for it based on differences in bioavailability.

Section 1. The following have been determined by the board to be noninterchangeable: drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration not to be therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations."

Section 2. The following have been determined by the board to be noninterchangeable unless the United States Food and Drug Administration considers them therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations":
(1) Digitalis glycosides;
(2) Antiepileptic drugs;
(3) Antiarrhythmic agents;
(4) Conjugated estrogens;
(5) Esterified estrogens;
(6) Warfarin anticoagulants;
(7) Theophylline products; and
(8) Thyroid preparations.

Section 3. "Approved Drug Products with Therapeutic Equivalence Evaluations," 11th Edition, 1991, U.S. Food and Drug Administration is incorporated by reference. (16 Ky.R. 1720; Am. 2154; eff. 5-13-90; 17 Ky.R. 2212; 2725; eff. 4-5-91.)